CDC's Division of Laboratory Systems Update

Collette Fitzgerald, PhD

Associate Director for Science Division of Laboratory Systems April 10-11, 2018

Excellent Laboratories, Outstanding Health



About DLS



Our Work



QUALITY AND SAFETY SYSTEMS





INFORMATICS AND DATA SCIENCE

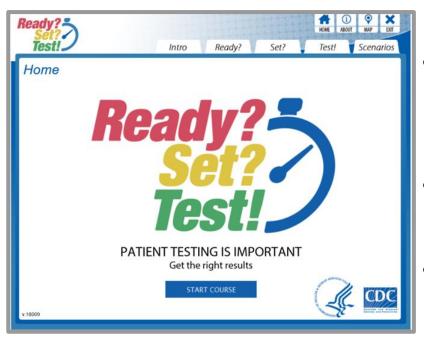


PREPAREDNESS



Quality and Safety Systems

Ready? Set? Test! Online Course – New Update Available



- Course is available free on CDC TRAIN and offers free CE
- Knowledge check questions throughout the course to reinforce learning
- Templates, checklists, resources to save/download
- Scenarios nursing home, hospital, doctor's office
- www.train.org/cdctrain/course/1056331

Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)

Clinical decision support tools

- Evaluation of partial thromboplastin time (PTT) Advisor mobile application accepted for publication in Journal of the American Medical Informatics Association
 - Contribute to better clinical laboratory test ordering and diagnosis and serve as a learning tool for diagnostic evaluation of certain bleeding and coagulation disorders.

Anticoagulation Manager mobile application available soon

- Resource for clinicians to appropriately order laboratory testing and choose anticoagulant drugs and dosage for patients
- Publication in the app store coming soon



Diagnostic Safety and Improvement

- Diagnostic Management Team (DMT) evaluation
 - Conduct an evaluation that will compare DMTbased diagnostic decision making and traditional, clinician-based decision-making

- Agency for Healthcare Research and Quality (AHRQ) Initiative
 - Establish a cross-agency research agenda for diagnostic safety and improvement



Next Generation Sequencing (NGS)



- Established a Tri-agency NGS workgroup
- Coordinating NGS quality efforts with other offices across CDC and Association of Public Health Laboratories (APHL) to improve implementation of NGS in public health laboratories
- NGS session held at last Clinical Laboratory Partners forum (Nov, 2017)

How best do we serve laboratory needs for assuring the quality of NGS testing?

Culture Independent Diagnostic Tests (CIDTs)

2018 CIDT Forum

- Meeting co-sponsored by Centers for Disease Control and Prevention, Association of Public Health Laboratories, PEW Charitable Trusts and Ohio State University
- May 8-9th, 2018 (Washington, D.C)
- Meeting goals
 - Increase stakeholder understanding about the opportunities and challenges associated with the adoption of CIDTs
 - Determine what critical public health information is being lost and what new information is gained due to implementation of CIDTs.
 - Generate new ideas and short-term / long-term strategies to fill gaps and address health data needs

New Initiative in Laboratory Biosafety

www.cdc.gov/SafeLabs



- New CLSI project to develop guidance for decontamination of laboratory equipment
 - Approved by CLSI Consensus Council in January 2018
 - Kick-off meeting scheduled for June 2018
 - Co-Chairs are James Snyder and Nick Solimo
 - Expected publication date February 2021

www.cdc.gov/labquality



Laboratories are on the frontline for protecting our communities' health. CDC provides clinical and public health laboratories with training and technical assistance to help them achieve the highest-quality laboratory science while ensuring the safety of laboratory professionals and the communities where they work. Learn more about CDC's laboratory quality efforts.



CLINICAL LABORATORY
IMPROVEMENT AMENDMENTS
(CLIA)



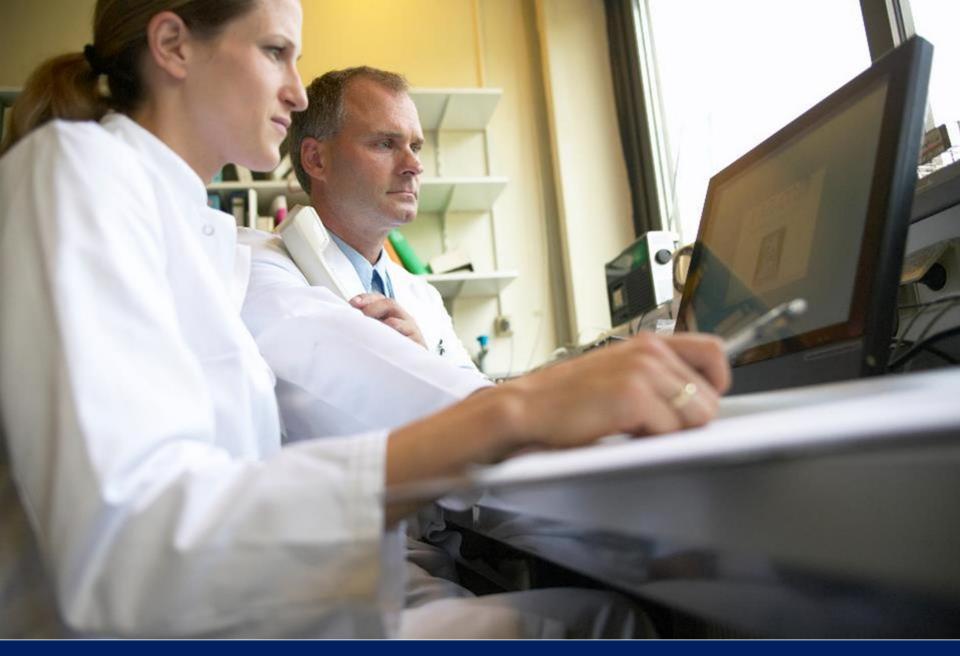
LABORATORY MEDICINE BEST
PRACTICES
(LMBP**)



INDIVIDUALIZED QUALITY
CONTROL PLAN
(IQCP)



GENETIC TESTING REFERENCE MATERIALS COORDINATION PROGRAM (GET-RM)



Preparedness

DLS Advancing Laboratory Preparedness



Building Public-Private Partnerships



Strengthening Communications



Coordinating Federal Agencies

Clinical Laboratory Partnership Forum



Better health through laboratory medicine.



AMERICAN ASSOCIATION OF BIOANALYSTS







American Clinical Laboratory Association









CLINICAL AND LABORATORY STANDARDS INSTITUTE®







Accreditation. Education. Innovation





Strengthening Communications





- Enhance emergency response communications with clinical laboratories through LOCS (LOCS@cdc.gov)
- Distributed 14 laboratory advisories, updates, and alerts to 24 clinical partner organizations, representing 190 countries and over 160,000 members since July 2017
- Connecting communicators to collaboratively raise awareness of clinical and public health laboratory resources and information
- Reaching membership from 18 partner organizations
- Launched website, distributed first newsletter, and held partnership call

Improving Deployment and Implementation of EUA Assays

 CDC, FDA, and CMS workgroup formed for early coordination and continued communication



- Current action items
 - Finalize the charter and process for interagency coordination
 - Develop training for clinicians and epidemiologists on EUA assays
 - Encourage standardization of LOINC codes for EUA assays





Enhancing Laboratory Surge Testing

 Memorandum of Understanding (MOU) between Association of Public Health Laboratories (APHL), American Clinical Laboratory Association (ACLA), Council of State and and Territorial Epidemiologists (CSTE), and Centers for Disease Control and Prevention (CDC)

Objectives

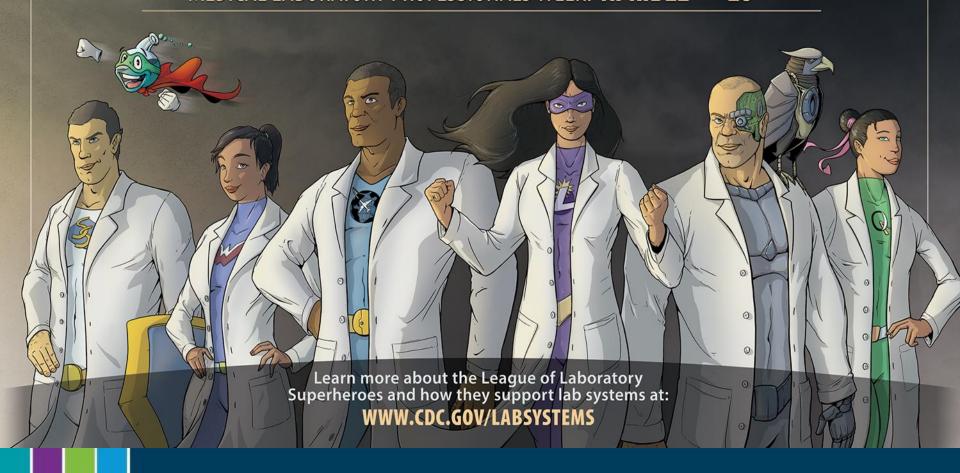
- Supplement public health laboratory testing capacity
- Improve coordination and communication
- Ensure commercial laboratories have access to appropriate resources
- Engage commercial laboratories early in the response to maximize resources
- Common understanding of test performance requirements, adherence to testing algorithms, and result reporting requirements



HEROES AMONG US...

DISGUISED IN LAB COATS

MEDICAL LABORATORY PROFESSIONALS WEEK: APRIL 22ND - 28TH



For more information, contact CDC 1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Images used in accordance with fair use terms under the federal copyright law, not for distribution.

Use of trade names is for identification only and does not imply endorsement by U.S. Centers for Disease Control and Prevention.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of Centers for Disease Control and Prevention.